

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES
BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Thomas Giudice, M.D.)

The plaintiffs filed their Notice of Adoption of Prior *Daubert* Motion of Thomas Giudice, M.D. for Waves 4 and 5 cases (“Notice”) [ECF No. 4541] in *In re C. R. Bard, Inc., 2:10-md-2187*, MDL 2187, on September 27, 2017. The plaintiffs attached as exhibits to their Notice a motion [ECF No. 4541-1], memorandum in support [ECF No. 4541-2], and reply brief [ECF 4541-3], which plaintiffs seek to adopt and incorporate as their briefing for Waves 4 and 5. Defendant also adopted and incorporated by Notice of Adoption of C.R. Bard, Inc.’s Prior Opposition to Plaintiffs’ *Daubert* Motion to Exclude Opinions of Thomas Giudice, M.D., for Wave 4 and Wave 5 cases, a brief in response to the plaintiffs’ Notice. [ECF No. 4639]. The court construes the plaintiffs’ Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs’ motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses,

and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

B Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and response in opposition. Similar to other *Dauberts* filed in the main MDL, the plaintiffs filed the instant motion as a “Notice,” adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. Defendant C. R. Bard, Inc. (“Bard”), likewise, filed its opposing briefs in conjunction with a similar “Notice.” The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to their respective Notice. So, for example, the plaintiffs attach the memorandum in support of their *Daubert* motion as “Exhibit 1” to their Notice. The plaintiffs also integrate into Exhibit 1 vital supporting papers, such as the expert report and deposition transcripts demarcated rather confusingly within Exhibit 1 as “Exhibit 1” and “Exhibit 2” respectfully, forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and

(1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct” – “[a]s with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); see also *Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness”

standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Bard offers Dr. Thomas Giudice, a practicing urogynecologist, as an expert witness on the use of transvaginal mesh and midurethral slings in the treatment of SUI and POP. The plaintiffs object to Dr. Giudice's opinions on certain subjects; including mesh shrinkage, mesh degradation, the Material Safety Data Sheets ("MSDS") for the polypropylene used by Bard, and AUGS/SUFU position statements.

A. Opinions on Mesh Shrinkage

Dr. Giudice opines in his expert report, "there is no scientific evidence that prolene mesh . . . contracts or shrinks." Notice of Adoption of Prior Daubert Mot. of Thomas Giudice, M.D., for Waves 4 & 5 Cases, Ex. 1 ("Giudice Expert Report") at 6 [ECF No. 4541-1]. The plaintiffs argue that this opinion is scientifically unreliable.

The reliability of an expert's opinion comes into question when he has not acknowledged or accounted for science that refutes his position. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.").

The plaintiffs argue that Dr. Giudice relies upon the Dietz study alone in support of his opinion that the mesh products do not contract or shrink, a study the plaintiffs believe includes evidence tending to refute this account. The plaintiffs point to a handful of purportedly opposing articles in their briefing that Dr. Giudice did not specifically mention in his expert report. In moving to exclude for these apparent deficiencies, the plaintiffs refer to parts of my *Daubert* opinion in *Tyree*. *See Tyree v. Bos. Sci. Corp.*, 2014 WL 5320566, No. 2:12-cv-08633, at *7 (S.D. W. Va. Oct. 17, 2014). In *Tyree*, the challenging party cited to particular portions of a particular expert's deposition testimony where he was asked about specific studies contrary to his opinion and, then, dismissed them in a conclusory manner without a scientific basis.

Here, the plaintiffs point to no such testimony and nothing in *Daubert* requires an expert to consider every single article on a topic in order to be admitted as an expert. *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) (observing that “[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an opinion”). In other words, the mere statement in Dr. Giudice's report that he believes there is “no scientific evidence that mesh shrinks or contracts” is hardly equivalent to a conclusory dismissal of refuting studies, particularly when the plaintiffs neglected to probe Dr. Giudice on his awareness of the refuting studies.

In sum, I decline to exclude Dr. Giudice solely for failing to comment on specific articles never presented to him for comment. *See id.* (“Generally, the test for exclusion

is a strict one, and the purported expert must have neither satisfactory knowledge, skill, experience, training nor education on the issue for which the opinion is proffered.”); *Kingsley v. Brenda & Gene Lummus, Inc.*, No. 1:11-CV-32, 2012 WL 727091, at *7 (W.D.N.C. Mar. 6, 2012) (stating that *Daubert* requires at bottom an “explanation . . . sufficient to permit others with similar training and experience to review his opinions and subject them to scientific testing”). The plaintiffs’ motion on this point is therefore **DENIED**.

B. Opinions on Mesh Degradation

The plaintiffs next object to Dr. Giudice’s opinion that he is “not aware of any medical literature or scientific information to support the theory polypropylene is not suitable for permanent implant in humans or that it degrades as a result of either oxygen or peroxides in the body or intraoperative contact, however minimal, with Betadine.” Giudice Expert Report, at 6. Here, on the same grounds as above, the plaintiffs move to exclude this opinion as unreliable.

On this topic, however, Dr. Giudice acknowledges certain limitations in his qualifications and fails to account for refuting literature.

Q: Well, you said in your report that you have seen no reference, literature of degradation, and yet, you refer to page 4 of this, an Ostergard study about degradation.

A: I’ve read that literature, correct.

Q: You just discount it?

A: Yes

Q: And your basis – your expertise to discount whether a polypropylene [mesh product] in the body degrades is what?

A: Based on other literature that I have reviewed in the past, based on my personal experience, based on other's reports and personal experience.

Q: Have – do you know, have you ever read any studies by Anderson about degradation?

A: I don't recall the name. I may have.

. . . .

Q: Is it fair to say you have no expertise in polymer degradation from a biochemical standpoint?

A: Correct.

Giudice Dep. at 145:2–18; 245:17–19

Regardless of Dr. Giudice's clinical experience with mesh implantation, and absent any appeal to supporting literature, his complete failure to explain his disagreement with refuting literature when presented with it, or even account for it, is decisive. *See, e.g., Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Ca. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted."); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

Therefore, Dr. Giudice's opinion that he is "not aware" of a body of literature is not "scientific, technical, or other specialized knowledge that will help the trier of fact to understand the evidence," Fed. R. Evid. 702, and the plaintiffs' motion on this point is **GRANTED**.

C. Opinions on the MSDS

Additionally, the plaintiffs move to exclude Dr. Giudice's opinion related to the utility of MSDSs. Dr. Giudice's opinion, in short, is that he has "seen no evidence that there is any scientific basis supporting the medical application caution language in the MSDS." Giudice Expert Report, at 13. *Daubert* bars expert testimony based on "belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Dr. Giudice, who has no knowledge about a manufacturer's considerations when drafting an MSDS, attempts to opine that because he did not see any evidence suggesting the MSDS has scientific roots, none exists. Such a speculative leap is improper for expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Therefore, the plaintiffs' motion on this point is **GRANTED**.

D. Opinions Regarding the AUGS/SUFU Position Statement

Finally, the plaintiffs object to Dr. Giudice's opinions regarding the AUGS/SUFU Position Statement. The Position Statement, according to the plaintiffs, is irrelevant, unreliable, and includes improper legal opinions that Dr. Giudice "parrots" in his report. *See* Notice of Adoption of Prior Daubert Mot. of Thomas

Giudice, M.D., for Waves 4 & 5 Cases, Ex. 1 (“Pls.’ Br. in Supp.”) at 15-17 [ECF No. 4541-1]). As an initial matter, I agree that Bard cannot use Dr. Giudice as a mouthpiece for the Position Statement—simply reading a document into evidence does not require “scientific, technical, or other specialized knowledge.” Fed. R. Evid. 702. Nor can Dr. Giudice represent to the jury that the Position Statement embodies a legal conclusion or a standard of care. *See United States v. McIver*, 470 F.3d 550, 572 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard . . . is generally inadmissible.”). To the extent Dr. Giudice seeks to use the Position Statement in this manner, Plaintiffs’ Motion is **GRANTED** and Dr. Giudice’s opinions are **EXCLUDED**.

The plaintiffs also argue that the Position Statement “is not a reliable scientific basis for any expert opinion” because it is litigation-driven and void of scientific analysis. *See* Pls.’ Br. in Supp., at 15. Even if this is true, the unreliability of one source used by an expert in reaching his opinion does not call for the exclusion of that opinion altogether, assuming the expert considered other reliable sources in his methodology. Therefore, to the extent the plaintiffs seek to exclude any of Dr. Giudice’s opinions merely because he relied, in part, on the Position Statement, their motion is **DENIED**.¹

IV. Conclusion

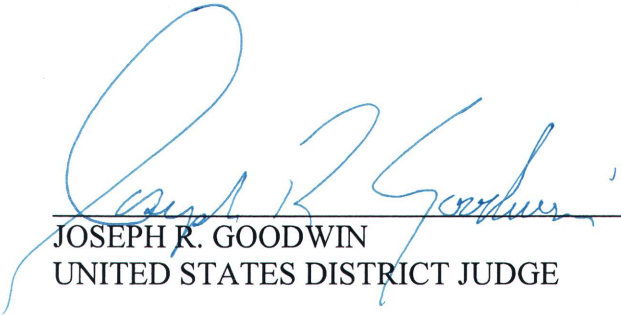
For the reasons stated above, the court **ORDERS** that the plaintiffs’ Notice of Adoption of Prior Daubert Motion of Thomas Giudice, M.D. for Waves 4 and 5 cases

¹ The plaintiffs also seem to argue that Dr. Giudice should not be permitted to reference the Position Statement at all. This argument goes to the admissibility of the Position Statement, rather than the admissibility of Dr. Giudice’s opinions, and is therefore better suited for a motion *in limine*. Accordingly, I do not address it at this time.

[ECF No. 4541], which has been construed by this court as a motion, is **GRANTED in part** and **DENIED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.